IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF OKLAHOMA

Charles Leon Manous, Surviving Spouse and Personal Representative of the Estate of Carol Ann Manous deceased,	)	
Plaintiff,	)	
v.	)	Case No. 5:11-cv-01330-R
Mylan Pharmaceuticals, Inc.,	)	
Defendant.	)	

JOINT STATUS REPORT AND DISCOVERY PLAN

Date of Conference: May 8, 2012 at 10:15 a.m.

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__X__ JURY TRIAL DEMANDED ____ NONJURY TRIAL

1. **BRIEF PRELIMINARY STATEMENT:** State briefly and in ordinary language the facts and positions of the parties to inform the judge of the general nature of the case.

This is a product liability case. Plaintiffs claim that Defendant's Fentanyl Patch was defective and unreasonably dangerous. Plaintiffs further contend that the Fentanyl patch delivered a fatal overdose of Fentanyl to Carol Ann Manous.

Mylan Pharmaceuticals Inc. ("MPI" or "Defendant") asserts that the Mylan Fentanyl Transdermal System® ("MFTS") is a generic drug product, approved by the Food and Drug Administration ("FDA") as "safe and effective" when used in accordance with its labeling. MPI asserts that its product is properly designed, properly manufactured, and was supplied with warnings and instructions which were more than adequate to ensure appropriate use of the product. MPI denies that any defect existed in the MFTS, and further denies that it caused or contributed to the death of Carol Ann Manous ("Decedent").

2. **JURISDICTION:** The basis on which the jurisdiction of the Court is invoked.

This Court has jurisdiction pursuant to 28 U.S.C. § 1332, diversity jurisdiction.

3. **STIPULATED FACTS:** List stipulations as to all facts that are not disputed or reasonably disputable, including jurisdictional facts.

A. Venue is proper in the Western District of Oklahoma.
B. Diversity jurisdiction applies to this case.

4. **CONTENTIONS AND CLAIMS FOR DAMAGES OR OTHER RELIEF SOUGHT:**

A. Plaintiff:

i. Mylan Pharmaceuticals, Inc. manufactures, markets, sells, and distributes the Fentanyl Transdermal System [hereinafter Fentanyl Transdermal System or Product].

ii. The Fentanyl Transdermal System is a device which delivers a predetermined amount of a pharmaceutical compound known as Fentanyl to a patient over a period of time.

iii. The Fentanyl Transdermal System is intended for use in the treatment of pain.

iv. On or about March 12, 2010, Carol Ann Manous was using the Fentanyl Transdermal System, which was manufactured, distributed, marketed and sold by Defendant Mylan Pharmaceuticals, Inc.

v. The Fentanyl Transdermal System was defective, delivered excessive amounts of Fentanyl to Carol Ann Manous, and caused Carol Ann Manous's death.

vi. The Board of Medicaolegal Investigations's Report of Laboratory Analysis shows that Carol Ann Manous had a blood concentration of Fentanyl of 28.1 ng/ml.

vii. A blood concentration of Fentanyl of 28.1 ng/ml is vastly in excess of the amount of Fentanyl that would have been delivered via a non-defective Fentanyl Transdermal System.

viii. A blood concentration of Fentanyl of 28.1 ng/ml is vastly in excess of the mean maximum concentration of Fentanyl that is delivered via the Fentanyl Transdermal System according to documents which Defendant Mylan Pharmaceuticals, Inc. has submitted to the United States Food and Drug Administration.

ix. The design characteristics of Defendant's Fentanyl patches is such that when they have been manufactured without defects, the serum Fentanyl concentrations resulting from a 100 mcg patch should not exceed approximately 5 ng/ml.

x. Mrs. Manous died as a result of an overdose of Fentanyl delivered by Defendant's defective patch.

xi. The medical examiner's report shows that the specific level of Fentanyl in Mrs. Manous's blood was 28.1 ng/ml.

xii. The characteristics of the subject patches, which delivered a dosage which achieved a level of 28.1 ng/ml rendered the Defendant's Fentanyl patches defective because they delivered a dosage substantially in excess of their intended design.

xiii. Defendant Mylan Pharmaceuticals, Inc.'s Fentanyl patches should have delivered a therapeutic, pain-relieving level of less than 5 ng/ml

of Fentanyl each to Mrs. Manous. That is the information which Defendant Mylan Pharmaceuticals, Inc. provides in its package inserts.

xiv. Instead, the Fentanyl patches at issue delivered a fatal dosage which reached a level of 28.1 ng/ml, surprisingly more than the designed dosage.

xv. Defendant's patches were defective and unreasonably dangerous. They delivered excessive amounts of Fentanyl in comparison to non-defective Fentanyl patches. They delivered excessive amounts of Fentanyl which were vastly more dangerous than would be contemplated by an ordinary consumer of the patches. They delivered excessive amounts of Fentanyl in comparison to the data supplied by Defendant Mylan Pharmaceuticals, Inc. to the United States Food and Drug Administration.

xvi. Far from being safe and effective, a position taken by Defendant Mylan Pharmaceuticals, Inc. in its FDA filings, the Fentanyl patches killed Mrs. Manous.

xvii. Defendant Mylan Pharmaceuticals, Inc.'s Product was in a defective condition which was unreasonably dangerous to the user, for which Defendant is strictly liable.

xviii. Defendant Mylan Pharmaceuticals, Inc. is in the business of manufacturing and selling pharmaceuticals in general and this Product in particular.

xix. Numerous claims have been made by those persons physically injured by Defendant's Product and those claims have brought awareness of the defects to Defendant.

xx. The Product was not reasonably fit for the ordinary purpose for which it was reasonably expected to be used because the Product was defective and dangerous to an extent beyond that which would be contemplated by the ordinary user or consumer who purchased it with the ordinary knowledge common to the community as to the product's characteristics.

xxi. The Product was unreasonably dangerous to a person who uses, consumes, or might be reasonably expected to be affected by the product.

xxii. The Product was defective at the time it was manufactured and sold by Defendant.

xxiii. Mrs. Manous recieved the product in sealed containers which had remained undisturbed since the time they were sealed by the Defendant.

xxiv. Plaintiff was a person who used, consumed, or could have reasonably

been affected by the Product.

xxv. Defendants acted intentionally and with malice, or in the alternative, with reckless disregard for the rights of others and with gross negligence. The Defendant's conduct in this case recklessly endangered Carol Ann Manous and the public in general in such a manner as to warrant the imposition of punitive damages.

xxvi. Carol Ann Manous would not have died if Defendant's Product had not been defective.

xxvii. Carol Ann Manous is survived by her surviving husband, Charles Leon Manous, by her children, Bo Tucker and Logan Manous, and by her father, Carl Franklin.

xxviii. Plaintiff should recover judgment for medical and burial expenses, loss of consortium and grief of the surviving spouse, mental pain and anguish suffered by the decedent, and grief and loss of companionship of the surviving children and parent of the decedent, plus punitive damages.

B. Defendant:

1. Defendant incorporates the claims, contentions, and defenses contained in their Answer and Affirmative Defenses as though set forth at length herein.
2. This case involves the alleged use of an FDA-approved generic pharmaceutical product, the MFTS.
3. Plaintiff is pursuing a manufacturing defect claim. (*See* Dkt. No. 23, Order, at 8.)
4. As with any pharmaceutical product, the manufacture and marketing of this product is controlled by the Food, Drug and Cosmetic Act ("FDCA"). Pursuant to statutory authority conferred on the FDA, MPI began to market the MFTS only after obtaining FDA approval of the drug.
5. In approving the product, the FDA determined that the MFTS is safe and effective in the management of persistent, moderate to severe chronic pain when the drug is used in accordance with its approved labeling.
6. MPI will demonstrate that no basis exists to challenge FDA's finding that the MFTS is a safe and effective drug product.
7. To the extent that Plaintiff can establish that Decedent was utilizing a MFTS at the time of her death, MPI denies that a purported defect in the MFTS was the proximate and/or a contributing cause of Decedent's death.

8. MPI will demonstrate that the claims raised by Plaintiff lack merit since the drug product in question was well designed, properly formulated, manufactured in accordance with good manufacturing practices, and reasonably safe when properly used and prescribed.
9. MPI will demonstrate: (i) the MFTS is safe and effective when properly used and properly prescribed; (ii) the product is safely and properly formulated, manufactured, distributed and sold; and (iii) no deficiency, defect, or malfunction exists in the MFTS which caused or contributed to the death of Decedent.
10. Finally, Plaintiff's reliance of post-mortem toxicology to establish or infer the existence of a defect in a transdermal drug product is scientifically invalid.
11. The concentration of fentanyl in dead blood measured hours or days after Decedent expired suggests nothing about the concentration of fentanyl in circulating blood during lifetime.
12. There is absolutely no credible evidence that the MFTS did anything other than deliver fentanyl at its prescribed rate. In fact, it is impossible for a single patch to achieve a rate of drug delivery that would result in a concentration of 28.1 ng/ml, as Plaintiff suggests.

5. **APPLICABILITY OF FED. R. CIV. P. 5.1 AND COMPLIANCE.**

Do any of the claims or defenses draw into question the constitutionality of a federal or state statute where notice is required under 28 U.S.C. § 2403 or Fed. R. Civ. P. 5.1? ___ Yes _X_ No

6. **MOTIONS PENDING AND/OR ANTICIPATED:** (include date of filing, relief requested, and date responsive brief to be filed.)

a. Plaintiffs:

1. No motions are pending.

2. Plaintiffs expect to file routine procedural and discovery related motions as well as motions in limine, according to the dates set by the Court's scheduling order.

b. Defendant:

1. No motions are pending.

2. MPI expects to file routine procedural and discovery related motions. In addition, MPI expects to file motions in limine, Daubert motions, and a motion for summary judgment in accordance with the Court's scheduling order.

7. **COMPLIANCE WITH RULE 26(a)(1)**. Have the initial disclosures required by Fed. R. Civ. P 26(a)(1) been made? ☐ Yes ☒ No

If "no," by what date will they be made? May 8, 2012

8. **PLAN FOR DISCOVERY**

A. The discovery planning conference (Fed.R.Civ.P. 26(f)) was held on April 18, 2012.

B. The parties anticipate that discovery will be needed for liability and damages issues and should be completed within 12 months.

C. In the event ADR is ordered or agreed to, what is the minimum amount of time necessary to complete necessary discovery prior to the ADR session? 11 months.

D. Have the parties discussed issues relating to disclosure or discovery of electronically stored information, including the form or forms in which it should be produced, pursuant to Fed. R. Civ. P. 26(f)(3)(c)? The parties do not anticipate any unusual difficulties in this regard.

E. To the extent the parties have made any agreements pursuant to Fed. R. Civ. P. 26(f)(3)(D) and Fed. R. Civ. P. 502(e) regarding a procedure to assert claims of privilege/protection after production and are requesting that the court include such agreement in an order, please set forth the agreement in detail below and submit a proposed order adopting the same.
Not applicable.

F. Identify any other discovery issues which should be addressed at the scheduling conference, including any limitations on discovery, protective orders needed, or other elements (Fed.R.Civ.P. 26(f)) which should be included in a particularized discovery plan. MPI documents which will be the subject of discovery include confidential, proprietary, and competitively sensitive materials. The parties plan to negotiate a form of a Protective

Order governing production of privileged materials and will submit the same to the Court for approval.

9. **ESTIMATED TRIAL TIME:** 5-10 days.

10. **BIFURCATION REQUESTED:** ☐ Yes ☒ No

11. **POSSIBILITY OF SETTLEMENT:** ☐ Good ☒ Fair ☐ Poor

12. **SETTLEMENT AND ADR PROCEDURES:**

A. Compliance with LCvR 16.3(c) – ADR discussion: ☒ Yes ☐ No.

B. The parties request that this case be referred to the following ADR process:
- ☒ Mediation
- ☐ Early Neutral Evaluation
- ☐ Non-Binding Arbitration
- ☐ Other _____

13. **Parties consent to trial by Magistrate Judge?** ☐ Yes ☒ No.

14. **Type of Scheduling Order Requested.** ☒ Standard ☐ Specialized.

The parties have conferred and believe that this is a complex case which will involve extensive fact discovery. In addition, there will be experts on both sides of the case. Because of the complexity of the litigation, the parties believe that the extended period of discovery outlined above is necessary and warranted.

Submitted this 2nd day of May, 2012.

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